REMARKS

Following this submission, claims 1, 3-6, and 8-22 are pending. Claim 13 has been withdrawn from consideration by the Examiner. Claims 1, 3-6, and 8-12 have been rejected. Claim 1 has been amended. Claims 14-22 have been added. New claim 14 depends from independent claim 12. New claims 15-22 recite features that do not appear in the cited art, and thus are asserted to be allowable over the cited art. In view of the discussion below, Applicants now believe that the application is in condition for allowance.

Elections/Restrictions

In the Office Action dated January 13, 2005, the Examiner withdrew claim

13 from consideration as being directed to a nonelected invention. Applicants had

requested reconsideration of the withdrawal of claim 13 in responding to that Office

Action. However, the Examiner did not acknowledge this request, or respond to it, in

the most recent Office Action dated July 26, 2005. Thus, Applicants here again request
reconsideration.

In particular, the Examiner stated (in the January 13, 2005 Office Action) that claim 13 is directed to an invention that is independent or distinct from the originally claimed invention because it recites a rearward extension with a knurled interior cavity, whereas the claims originally examined on the merits recite an extension that is enveloped by a coupling mechanism. Applicants respectfully request a reconsideration of the withdrawal of claim 13. In particular, Applicants note that independent claim 13

finds support in original claim 7, which was previously cancelled in favor of new claim 13. Thus, since the substance of claim 13 was present in the claims as originally —— examined on the merits, Applicants submit that new claim 13 would not require any further searching beyond that which has been performed by the Examiner regarding claim 7.

Claim Rejections 35 U.S.C. § 102

Nightingale (U.S. Patent No. 3,747,479)

The Examiner has rejected claims 1, 3-6, and 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,747,479, issued to Nightingale.

Nightingale had been used as a rejection of the same claims in two previous Office Actions (dated August 4, 2004 and January 13, 2005). In response to the August 4, 2004 Office Action, Applicants had argued that Nightingale does not disclose a rearward extension that is capable of being within an area enveloped by a coupling mechanism. In the January 13, 2005 Office Action, the Examiner disagreed and stated that Nightingale discloses a "rearwardly-facing drive ram engaging coupling element 72," and that this "extension from the plunger does have [the] capability [of being within an area enveloped by a coupling mechanism] due to its elongated structure." In the present Office Action, the Examiner has again maintained this rejection, and recited the same reasoning. Applicants disagree, respond as follows, and submit a Declaration of Frank M. Fago under 37 C.F.R. § 1.132, in support thereof.

As an initial matter, Applicants note that claim 1 recites (1) a "drive ram engaging coupling element" in the shape of a rearwardly facing extension on a plunger; (2) that the rearwardly facing extension is "knurled at least along the portion of said extension adapted to be within an area enveloped by a coupling mechanism," and (3) that the extension "does not extend outside of the cylindrical barrel in at least one position of the plunger." Claim 12 recites that "no two adjacent transverse crosssections of said rearwardly facing extension exhibit discontinuity . . . along the portion . . . adapted to be within the area enveloped by a coupling mechanism."

Applicants submit that Nightingale does not anticipate claim 1 for at least the following reasons: (1) Nightingale does not disclose a "drive ram engaging coupling element"; (2) any drive ram engaging coupling element added to Nightingale would destroy the function of Nightingale; and (3) any drive ram engaging coupling element added to Nightingale would cause the extension of Nightingale to extend outside the syringe barrel in all positions of the plunger (contrary to the recitations of claim 1).

Applicants further submit that Nightingale does not anticipate claim 12 at least because the extension of Nightingale exhibits a discontinuity along the portion adapted to be within the area enveloped by a coupling mechanism, contrary to the recitations of claim 12.

Turning first to the rejection of independent claim 1 (and thus dependent claims 3-6): Nightingale is directed to a piston assembly that is used in syringes and stopcocks. In particular, Figure 7, which is pointed to by the Examiner in rejecting claim

1 (and claim 12), is of a syringe including the piston assembly. As can be seen from that Figure, the threaded sleeve 72 (which the Examiner considers to be a "rearwardly-facing drive ram engaging coupling element") is already coupled to a mechanism to move the plunger within the syringe barrel: an operating bar 79 and mandrel 73, which extend through the threaded sleeve 72. Applicants submit that this operating bar and mandrel are not a <u>drive ram</u>, as is found on injectors such as those described in the present application. Thus, Applicants submit that the threaded sleeve 72 cannot be a "<u>drive ram</u> engaging coupling element" as recited by claim 1.

Applicants had-previously made a similar argument in responding to-the January 13, 2005 Office Action. In the July 26, 2005 Office Action, the Examiner responded to Applicants' argument by saying that claim 1 does not recite a "drive ram." However, Applicants never argued for claim 1 based on any recitation of a "drive ram." Rather, Applicants argued that Nightingale does not disclose a "drive ram engaging coupling element." This element is recited in claim 1, and would inherently require a drive ram in order to render the element a "drive ram engaging coupling element." However, since Nightingale does not disclose a drive ram, it cannot disclose a drive ram engaging coupling element. (See the attached Declaration of Frank M. Fago, para. 5.)

Further, even if one were to assume, for the sake of argument, that the operating bar and mandrel form a drive ram (which Applicants submit they do not),

Applicants assert that the knurled portion of the threaded sleeve 72 is not "adapted to be within an area enveloped by a coupling mechanism." This is because there is no

enveloping coupling mechanism disclosed by Nightingale. Rather, as is clear from Fig. 7, there is already a mechanism coupled to the extension in Nightingale: the operating bar 79 and mandrel 73. If one were to envelope the knurled area of the rearward facing extension of Nightingale, one would block off the opening that is used to receive the operating bar 79 and mandrel 73. In such a configuration, elements of the apparatus would have to be removed from Nightingale's disclosure, and the function of the apparatus of Nightingale would be destroyed. (For further support, see the attached Declaration of Frank M. Fago, para. 6).

Further, again referring to Fig. 7 of Nightingale, even if one were to assume, for the sake of argument, that the extension of Nightingale <u>could</u> be enveloped with a coupling mechanism (which Applicants submit it could not, since to do so would ignore elements of Nightingale and destroy the function of Nightingale), Applicants assert that the extension could not then be received within the barrel of the syringe shown in Fig. 7 (due to the small clearance between the threaded sleeve and syringe barrel). (See attached Declaration of Frank M. Fago, para. 7). In such a configuration then, Nightingale's extension would need to be lengthened so that at least a portion of the extension would remain outside the syringe barrel in <u>all</u> positions of the plunger – otherwise, there would be no way to envelop the coupling mechanism. However, if thus modified, Nightingale would not satisfy the limitation in claim 1 that the rearwardly facing extension "does not extend outside of said cylindrical barrel in at least one position of said plunger."

In view of the above, Applicants asset that claim 1 is not anticipated by Nightingale. Since claim 1 is not anticipated, Applicants further assert that claims 3-6 (each ultimately dependent from claim 1) are also not anticipated by Nightingale.

Turning now to the rejection of independent claim 12: As described above, even if one were to envelope the extension of Nightingale with a coupling mechanism (which Applicants submit one would not), the extension could not then be received within the barrel of the syringe due to the small clearance. Thus, Nightingale's extension would have to be modified to remain outside the syringe in <u>all</u> positions of the plunger. However, thus modified, Nightingale would not satisfy the limitation in claim 12 that he extension "does not extend outside of said cylindrical barrel in at least one position of said plunger."

Also, still considering that one could assume that the extension of Nightingale could be enveloped with a coupling mechanism (which Applicants submit it could not), Applicants assert that the extension would include discontinuities in adjacent cross-sections in the area enveloped by the coupling mechanism. In fact, in the July 26, 2005 Office Action, the Examiner admits that there is a discontinuity shown in Nightingale, but states that it is not within "an area" enveloped by a coupling mechanism. The Examiner distinguishes this from "the area" enveloped by the coupling mechanism. However, the Examiner seems to be mistaken in that claim 12 already recites "the area." And, as can be seen in Figure 7 of Nightingale (and as the Examiner acknowledges in the third paragraph of page 4 of the July 26, 2005 Office

Action), there is a discontinuity within this area. Thus, Nightingale would not satisfy the limitation that "no two adjacent transverse cross-sections of said rearwardly facing extension exhibit discontinuity . . . along the portion . . . adapted to be within the area enveloped by a coupling mechanism" as recited by claim 12.

In view of the above, Applicants respectfully request a withdrawal of the rejection of claims 1, 3-6, and 12 under 35 U.S.C. § 102(b) as anticipated by Nightingale.

Reilly (U.S. Patent No. 4,677,980)

The Examiner has further rejected claims 1, 3-6, and 8-11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,677,980, issued to Reilly. Applicants respectfully-disagree.

Regarding claims 1 and 3-6, Applicants note that independent claim 1 recites that the rearwardly facing extension is knurled at least "along the portion of said extension adapted to be within the area enveloped by a coupling mechanism." The Examiner has stated-(in the January 13 and July 26, 2005 Office Actions) that the common definition of a knurl is "a protuberance, as a knob or knot," or "one of a series of small ridges." Applicants agree with the Examiner that knurls can be a "series of small ridges," and that such knurls are disclosed in the present application (see at least Figs. 4A-4C of the present application). As can be seen from the disclosure of the application, these sorts of knurls provides extra friction to facilitate gripping between two surfaces, but do not form any interlocking engagement between the two surfaces. (See

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also Declaration of Frank M. Fago, para. 9). Thus, claim 1 has been presently amended to recite that the knurls "are not adapted to interlockingly engage with said coupling mechanism." Applicants submit that the apparatus disclosed in Reilly does not satisfy this limitation.

Only in Figs. 17 and 20 does Reilly explicitly show a coupling mechanism enveloping a rearwardly facing extension. However, Applicants submit that the rearward facing extension of Fig. 20 is not knurled, in that it does not include a series of ridges or grooves, as recited by claim 1. And, Fig. 17 does not show ridges or grooves that are not adapted to interlockingly engage with a coupling mechanism. Referring to Fig. 17 and the disclosure at column 10, lines 4-31, Applicants submit that the structures shown in Fig. 17 on the extension are a plurality of raised screw-type threads (160), which define a plurality of incline channels (162) therebetween. The screw-type threads (160) are designed to interact with a hook member (170), which is fixedly mounted on the right angle member of a hook assembly (166) of the coupling mechanism (also shown in Figs. 18 and 19). In use, as the drive mechanism, including the coupling mechanism, is advanced by the drive piston, the hook-shaped members (170) enter respective one of the channels (162) between the screw threads (160). As this happens, the hook members pass through the channels. Eventually, the outer ends of the hook assemblies (166) engage the extension on the plunger. In other words, the configuration of hooks on the coupling mechanism and threads on the extension engage to form an interlocking engagement to hold the syringe plunger to the

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drive ram. (See also Declaration of Frank M. Fago, para. 10). Applicants thus submit that Reilly fails to disclose each and every claimed element of the present application in claim 1, as presently amended. Applicants thus submit that claim 1 is not anticipated by Reilly. Since claim 1 is not anticipated, Applicants further submit that dependent claims 3-6 are also not anticipated by Reilly. Applicants therefore respectfully request a withdrawal of the rejection of claims 1 and 3-6 as being anticipated by Reilly under 35 U.S.C. § 102(b).

Regarding claims 8-11, Applicants note that independent claim 8 recites that "no two adjacent transverse cross-sections of said rearwardly facing extension exhibit discontinuity in area when compared to one another along the portion of said extension adapted to be within the area enveloped by said coupling mechanism."

Applicants previously argued that all embodiments of Reilly, including rearward extensions enveloped by a coupling mechanism, include some discontinuity between two adjacent cross-sections within the area enveloped.

However, in the present Office Action, the Examiner states that Figure 16 of Reilly shows a rearward extension having no discontinuities. The Examiner also states that "discontinuities" requires adjacent cross-section having diameters of "much greater cross-section" (citing comments Applicants made at page 17 of the response dated April 13, 2005). The Examiner states that Reilly does not show adjacent cross-sections of "much greater diameter," and thus does not exhibit discontinuities.

Applicants respond as follows. First, regarding Figure 16, Applicants

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assume that the Examiner is looking to the sloped side of the notch in Figure 16 of Reilly, and determining that a gradual-slope would not result in "much greaterdifference" between adjacent cross-sections. However, the Examiner ignores the nonsloped side of the notch, which does show a "much greater diameter" between two adjacent cross-sections. Any coupling mechanism interacting with the Figure 16 structure would clearly envelope the nonsloped side of the notch. Second, regarding the "much greater diameter," the Examiner misunderstands Applicants' comments at page 17 of the April 13, 2005 response. When Applicants made those comments, Applicants merely argued that a cited reference (Neer) shows much greater diameter in adjacent cross-sections, and thus shows discontinuity. However, Applicants never said that all discontinuities must have a "much greater diameter." All that is recited is that no two adjacent transverse cross-sections of the rearwardly facing extension exhibit discontinuity in area when compared to one another along the portion of the extension adapted to be within the area enveloped by the coupling mechanism. In Figure 16 of Reilly, such discontinuities are formed in both the sloped and the nonsloped sides of the notch.

Applicants thus submit that claim 8 is not anticipated by Reilly. Since claim 8 is not anticipated, Applicants further submit that dependent claims 9-11 are also not anticipated by Reilly. Applicants therefore respectfully request a withdrawal of the rejection of claims 8-11 as being anticipated by Reilly under 35 U.S.C. § 102(b).

¹ This argument should <u>not</u> be taken as an admission on Applicants' part that "discontinuities" require a "much greater diameter," as will be discussed later.

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Conclusion

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

The Commissioner is authorized to charge Deposit Account No. 23-3000 in the amount of \$790.00 for the fee due under 37 C.F.R. § 1.17(e) for a Request for Continued Examination. Further, in view of the addition of new claims 14-22, the Examiner is authorized to charge Deposit Account No. 23-3000 in the amount of \$500.00 for two claims in excess of twenty and two independent claims in excess of three, under 37 C.F.R. §§ 1.16(i) and (h). If any additional fee or surcharges are deemed due, please charge same or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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